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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
|-----------------|-------------|----------------------|---------------------|------------------|

10/535,529

05/09/2006

Samir F. Saba

UPITT-09379

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23535 7590 06/09/2009
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EXAMINER

EVANISKO, GEORGE ROBERT

ART UNIT

PAPER NUMBER

3762

MAIL DATE

DELIVERY MODE

06/09/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|---------------------------------------|---------------------------------------|--|
| Office Action Summary | Application No. 10/535,529 | Applicant(s) SABA, SAMIR F. | |
| | Examiner George R. Evanisko | Art Unit 3762 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 March 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 27-29, 31 and 33-35 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 27-29, 31, 33-35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 27-29, 31, and 33-35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 27, “an implantable pacemaker comprising a plurality of pacing leads configured....” is vague and it is unclear if there is actually a pacemaker, if there is a pacemaker and leads, or if the pacemaker is just the pacing leads since the claim uses “comprising” which further defines a previous element. If the pacemaker is meant to “further comprise” the leads, it is suggested to use “further comprising”. In addition, it is unclear if “...leads configured...” is meant to define the leads or the pacemaker (i.e. is it the lead or the pacemaker that is configured to deliver the simultaneous pulses?). The examiner has interpreted it to be the leads since “configured” modifies the “leads”. It is noted that all independently addressed leads can deliver simultaneous pacing. In element b) and c), "said pacemaker element" lacks antecedent basis. In addition, it is unclear if the ventricular and atrial leads are in addition to the pacing leads or whether they are the same or whether these leads refer to “electrodes” (figure 1 seems to show that they are the same and therefore can't be claimed as separate elements). In step c), "said implantable defibrillator comprising a timing device" is vague (similar to the "pacemaker comprising...leads") since it is unclear if there is a defibrillator, a defibrillator and timing device, or just a timing device.

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In claims 28 and 22, “said pacemaker element” lacks antecedent basis.

Claim 31 is vague since it further comprising ADDITIONAL leads. Now the claims contain 6 leads. It is unclear if the leads are the same leads or different leads (note, an “electrode” is different than a “lead”).

Claim Rejections - 35 USC § 102 and 103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 27-29, 31, 33, and 34 are rejected under 35 U.S.C. 102(e) as anticipated by Kupper (6813518), or in the alternative under 35 U.S.C. 103(a) as being unpatentable over Kupper. Kupper discloses a pacemaker/defibrillator to deliver simultaneous pacing burst pulses to the atrium and ventricle when a tachycardia is detected (e.g. abstract, figures 6, 7, col. 11, line 53) using multiple leads/electrodes and thereafter senses for the first atrial or ventricular depolarization (e.g. col. 11, line 64, figure 3, element 74/58) to determine the first depolarization

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to provide different intervals (e.g. escape intervals, col. 10). NOTE, the claim does not state that the determination of the depolarization is used to classify the origin of the arrhythmia.

In the alternative, for the multiple sensing, pacing, and defibrillation leads (i.e. the catheter/lead body for containing the conductors and electrodes). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the IMD as taught by Kupper to include the multiple sensing, pacing, and defibrillator leads since it was known in the art that IMDS use multiple sensing, pacing, and defibrillation leads to provide the predictable results of easily and accurately placing the different leads and electrodes in the heart at the proper locations for the patient's particular condition.

Claim 35 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kupper. Kupper discloses the claimed invention except for the quadripolar sensing lead. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the IMD as taught by Kupper, with the quadripolar sensing lead since it was known in the art and the examiner is taking official notice that IMDs use quadripolar sensing leads to provide the predictable results of allowing multiple areas of the heart to be sensed with one lead by inserting a minimal number of leads and therefore providing less trauma/problems to the heart.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re*

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Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 27-29, 31, and 33-35 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-17 of U.S. Patent No. 7206633. Although the conflicting claims are not identical, they are not patentably distinct from each other because the patented claims meet the limitations of this application's claims. In addition, it would have been obvious to one having ordinary skill in the art at the time the invention was made to include the simultaneous ATP pulses in the patented claims, since it was known that simultaneous ATP pulses are delivered with an IMD to provide the predictable results of therapy and coordination of the heart muscle.

Response to Arguments

Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection necessitated by amendment. The NUMEROUS arguments that the applicant "disagrees" are not persuasive. Applicant's arguments fail to comply with 37 CFR 1.111(b) because they amount to a general allegation that the claims define a patentable invention without specifically pointing out how the language of the claims patentably distinguishes them from the references. In addition, Applicant's arguments do not comply with 37 CFR 1.111(c) because they do not clearly point out the patentable novelty which he or she thinks the claims present in view of the state of the art disclosed by the references cited

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or the objections made. Further, they do not show how the amendments avoid such references or objections.

The argument that Kupper does not “determine the source of the depolarizations” is not persuasive since the claims only state that the timing device determines the earliest arriving signal from the atrial or ventricular lead and NOT determines the source of the depolarization.

The arguments that “the microprocessor of Kupper et al merely detects” the next electrical event, but does not and cannot distinguish between the two, and that “the disclosed escape intervals of Kupper et have” no bearing on the claims and are irrelevant, are not persuasive. Kupper senses/detects the next (the FIRST) depolarization after the blanking period/burst and therefore senses AND determines the claimed "earliest arriving electrical signal" by the atrial or ventricular lead since Kupper must start the appropriate escape interval based on the sensed depolarization. Kupper does not (and will not) just start any escape interval, but must start the appropriate atrial or ventricular interval based on the first/earliest arriving atrial or ventricular electrical signal (e.g. col. 9, line 65 to column 10, line 67).

The arguments regarding the non-statutory ODP are not persuasive. Although the 7206633 patent claims a method, the method claims set forth that structure is provided. In addition, although the patent and this application may have priority to the same date, a TD will still need to be filed since a TD is not only used for improper timewise extensions, but for preventing separate licensing of similar/unobvious inventions between two patents.

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Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to George R. Evanisko whose telephone number is 571 272 4945. The examiner can normally be reached on M-F 6:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571 272 4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/George R Evanisko/
Primary Examiner, Art Unit 3762

GRE
6/7/09